PATENT COOPERATION TREAT

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing (*day/month/year*) 05 DEC 2005	
Applicant's or agent's file reference 8702.097-304	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date (*day/month/year*)
PCT/US03/23981	01 August 2003 (01.08.2003)	02 August 2002 (02.08.2002)

Applicant

WYETH

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US	Authorized officer
Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	Maryam Monshipouri
Facsimile No. (703) 305-3230	Telephone No. 571-272-1600

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 8702.097-304	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/23981	International filing date *(day/month/year)* 01 August 2003 (01.08.2003)	Priority date *(day/month/year)* 02 August 2002 (02.08.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): C12N 9/12, 1/20, 15/00; C07K 1/00, 21/02, 21/04 and US Cl.: 435/194, 320.1, 252.3; 536/23.2, 23.1; 530/350		
Applicant WYETH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27 February 2004 (27.02.2004)	28 October 2005 (28.10.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Maryam Monshipouri Telephone No. 571-272-1600

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRE[redacted]NARY EXAMINATION REPORT

International [redacted]plication No.
PCT/US03[redacted]1

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed.

☒ the description:
pages 1-64 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages NONE, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages 65-72, filed with the letter of 02 April 2004 (02.04.2004).

☒ the drawings:
pages 1-20, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the sequence listing part of the description:
pages 1-15, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☒ contained in the international application in printed form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRE[redacted]NARY EXAMINATION REPORT

International [redacted]plication No.
PCT/US03/[redacted]981

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 12-19 and 21-50

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 12-19 and 21-50

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRE[redacted]NARY EXAMINATION REPORT

International [redacted]plication No.
PCT/US0[redacted]1

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-11, 20, 51-60	YES
	Claims	NO
Inventive Step (IS)	Claims 10-11, 20, 57, 59	YES
	Claims 1-9, 51-56, 58, 60	NO
Industrial Applicability (IA)	Claims 1-11, 20, 51-60	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-9, 51-56, 58 and 60 lack an inventive step under PCT Article 33(3) as being obvious over Huang (cited previously) in view of Kramer (cited previously) optionally in view of kit preparation techniques. Huang teaches a protein complex composed of MAPKAP kinase 2 (MK2), which may be considered to be a homolog of SEQ ID NO:4-6 and LSP1 (its major substrate, a heat shock protein designated p60), Both serine target residues of LSP1 (i.e. serine 204 and serine 252) are located in the C terminal F-actin binding domains.

Huang does not teach a complex composed of MK2 and Smoothelin homologs (such as STS).
Kramer teaches novel isoforms of smoothelin which can be considered to be STS. They also teach the amino acid sequences of said isoforms which all indicate an F-actin binding domains at their C-terminals (see figure 1).

At the time the invention was made it would have been obvious to start with MK2 protein of Huang and try to form a complex between MK2 and STS proteins of Kramer according to teachings of Huang in order to identify whether STS protein(s) are also involved in heat shock triggered or cell proliferation processes. One of ordinary skill in the art is motivated in identifying novel substrates for MK2 because said substrates may be utilized in drug design in combating cancer etc., rendering claims 1-9, 58 and 60 obvious. Such method inherently requires buffers comprised of STS/MK2 complexes and said buffers may be considered to be pharmaceutical compositions comprising said protein complexes, rendering claim 55-56 obvious.

Finally even though Huang in view of Kramer does not teach kits comprising said Mk2/STS complexes and at least one buffer or one structural component, current kit preparation techniques teach that once one of skill in the art identifies a substrate of a well known MAPkinase protein such as MK2, it is merely routine to place said substrate together with solutions (such as kinase buffers etc.) into a kit according to current kit preparation techniques in order to be able to readily identify agents that interfere with the MK2 and said substrate binding etc., rendering claims 51-54 obvious.

Claims 10-11, 20, 57-59 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest host cells comprising DNA sequences encoding recombinant MK2/STS complexs specially with the MK@ amino acid sequences as set for as SEQ ID NO:4-6.